

3314 W. Columbus Dr. Tampa, FL 33607-1820 USA August 4, 1999 FAX: (813) 881-9216 Phone: (813) 880-9183

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. S.W. Washington, DC 20204

RE: Compliance with Food Labeling; Notification Procedures for Statements on Dietary Supplements.

Dear FDA Consumer Safety Officer,

In compliance with the new food labeling ruling requiring distributors of dietary supplements to notify FDA that they are marketing a dietary supplement product that bears on its label a statement provided by section 403(r)(6), the following is herein stated:

(i). The name and address of the distributor of the dietary supplement "ProstaMed" is:

NutriMed, Inc. 3314 W. Columbus Dr. Tampa, FL 33607-1820, U.S.A.

- (iii). The name of the dietary ingredients that are the subject of the statements being made are:
  - Zinc 10 mg
  - Saw Palmetto berries 110 mg (standardized)
- (iv). The name of the dietary supplement on whose label the statement appears is "ProstaMed" and the brand name is "NutriMed."
- (v). The product "ProstaMed" contains the following prominently displayed, boxed, and boldface type statement:
  "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- (vi). The product was first marketed on June 10, 1999, in the State

1

of Florida by NutriMed, Inc.

(vii). I, Dr. Idel Suárez, Jr., Ph.D., M.S., R.D., as President of NutriMed, Inc., and as a qualified nutrition professional certify that the information above presented is complete and accurate, and our firm is able to substantiate that the statement is truthful and not misleading.

A monograph, which reviews the scientific literature and substantiates the claims made on ProstaMed as a supplement for prostate well-being is on file and available upon request.

Sincerely,

Dr. Idel Suarez Jr., Ph.D., M.S., R.D.

President of NutriMed, Inc.

Enclosure

An original and two copies are included

[FDA4.899]